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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/956,980	09/21/2001	Ashley I. Bush	0609.4550001/JAG/FRC	6687
26111	7590	03/05/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			WEDDINGTON, KEVIN E	
			ART UNIT	PAPER NUMBER

1614

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
09/956,980	BUSH ET AL.	
Examiner	Art Unit	
Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10, 11, 25, 26, 40, 41 and 58-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 11, 25, 26, 40, 41 and 58-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11-10-03</u> . | 6) <input type="checkbox"/> Other: _____ |

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Claims 10, 11, 25, 26, 40, 41 and 58-63 are presented for examination.

Applicants' information disclosure statements filed May 2, 2003 and November 10, 2003 and the amendment filed November 10, 2003 have been received and entered.

Accordingly, the rejection made under 35 USC 102 as set forth in the previous Office action at page 4 is hereby withdrawn.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 10, 11, 25, 26 and 58-61 are again rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 2, 10 and 11 of prior U.S. Patent No. 6,323,218.

Applicants' remarks regarding the present application is a divisional of U.S. Patent No. 6,323,218 and states under 35 USC 121, the '218 patent cannot be used in a double patenting rejection (statutory or obviousness-type) against the claims in the currently pending application are not persuasive since the present application claims 10, 11, 25 and 26 teaches the chelator specific for copper is bathocuproine; and the patented application teaches the metal chelator is selected from bathocuproine too. Clearly, the two applications read on the same invention, a method of treating amyloidosis in a subject with a combination of a chelator specific for copper (same as a metal chelator) and clioquinol. Also not the hydrophobic derivatives of a chelator specific for reduced form of copper (same as metal chelator) can be combined with clioquinol.

This is a double patenting rejection.

Claims 10, 11, 25, 26 and 58-61 are not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 11, 25, 26, 40, 41 and 58-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the instant method, claims 10 and 25 fail to particularly point out the identity of the active agent (a chelator specific for copper) to be administered in the instantly claimed method. The current claim language is drawn to administering a compound, which is not described structurally/formulaically/nomenclatorially; however, the active agent's (a chelator specific for copper) mode of action, function or effect requisite to practicing the claimed method set forth. The claims are missing the critical element, which is particular or distinct identity of the active agent (a chelator specific for copper) to be used in the method claims. It is noted the claims are limited to what the administration or use of "a compound" is intended to accomplish rather than what the active agent (a chelator specific for copper) actually represents as chemical entity.

In the instant method claims 58 and 60 fail to particularly point out the identity of the active agent (a hydrophobic derivative of a chelator specific for the reduced form of copper) to be administered in the instantly claimed method. The current claim language is drawn to administering a compound, which is not described structurally/formulaically/nomenclatorially; however, the active agent (a hydrophobic derivatives) mode of action, function or effect requisite to practicing the claimed method set

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forth. The claims are missing the critical element, which is particular or distinct identity of the active agent (a hydrophobic derivative) to be used in the method claims. It is noted the claims are limited to what the administrated or use of "a compound" is intended to accomplish rather than what the active agent 9a hydrophobic derivative) actually represents as chemical entity.

In the instant compound/composition, claim 40 fail to particularly point out the identity of the component described as a chelator specific for copper. The current claim language is drawn to an activity or desired property of a compound/composition. This language does not particularly or distinctly provides sufficient clarity regarding the structural/formulaic/nomenclatorial identity of the chemical core applicants intended to represent as a component of the comp/compstn articulated in the claim.


In the instant compound/composition, claim 62 fail to particularly point out the identity of the component described as a hydrophobic derivative of a chelator specific for the reduced form of copper. The current claim language is drawn to an activity or desired property of a compound/composition. This language does not particularly or distinctly provides sufficient clarity regarding the structural/formulaic/nomenclatorial identity of the chemical core applicants intended to represent as a component of the comp/compstn articulated in the claim.

The remaining claims are rendered indefinite to the extent that they incorporate the above terminology.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571) 272-0587. The examiner can normally be reached on 11:00 am-7: 30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-1235. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
March 3, 2004